Bu

- 125. The system of claim 122 wherein the sample vessels are capillary tubes each having an inner diameter ranging from about 0.02 mm to about 1.0 mm.
- 126. The system of claim 124 wherein the passageway of the carousel includes a barrier that prevents a liquid sample delivered through the sample receiving port from flowing to the sample vessel port absent a biasing force on said liquid sample.
- 127. The system of claim 124 further comprising a motor for rotating the carousel to provide a biasing force on a liquid sample delivered through the sample receiving port.

## **REMARKS**

Claims 118-127 have been added. New claims 118-121 and 122-127 are similar to claims 79-82 and 87-92, respectively. However, the new claims do not require that the light source and detector be mounted inside the chamber as in claims 79-82 and 87-92. Support for new claims 118-127 can be found in the specification at page 99, line 2 through page 106, line 6 and in Figures 11, 21, and 28. No new matter has been added by way of addition of any of these claims. Passage of these claims to allowance is respectfully requested.

Applicants have carefully reviewed the Office Action mailed on November 9, 1999. As requested by the Examiner, applicants have amended page 2 of the specification to specify the relationship of the instant application to related applications, and applicants have amended the specification on page 3 to include the serial number of the copending U.S. Patent application filed on June 4, 1997.

Claims 13, 16-18, 25, 27-28, 33, 35, 55-59, 79-82, 87, and 90 have been amended to clarify terms and to correct informalities. No new matter has been added by way of these amendments.

The Examiner has rejected claims 13-35, 55-59, 79-82, and 87-92 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicants regard as their invention. Specifically, the Examiner has rejected claims 13, 18 and 33 as being vague and indefinite because these claims contain volume limitations which are not directed clearly to the sample container versus the optically clear material (claims 13 and 33), or to the sample container versus the glass portion of the sample container (claim 18). Applicants have amended claims 13, 18, and 33 to point out more particularly that the volume limitation is directed to the sample container. No new matter has been added by way of these amendments. The amendments to claims 13 and 18 are believed to be fully responsive to the Examiner's rejection of these claims, as well as to the rejection of dependent claims 14, 15, 19-24, 26, and 29-32.

Although the Examiner has rejected claim 33 under 35 U.S.C. § 112 for additional reasons, the amendment to claim 33 is believed to be fully responsive to the Examiner's rejection of claim 33 on this basis, as well as to the rejection of dependent claims 34 and 35. Withdrawal of these rejections is respectfully requested.

The examiner has rejected claims 16 and 17 because the Examiner contends that the relationship between the control means of claim 13 and the control mechanisms of claims 16 and 17 is unclear. Applicants have amended claims 16 and 17 by replacing the phrase "further comprising a control mechanism" with "in which the control means." Applicants have made this amendment to point out more particularly that the control means of claim 13 performs the additional operation of claims 16 and 17. No new matter has been added by way of these amendments. The amendments to claims 16 and 17 are believed to be fully responsive to the Examiner's rejection of these claims. Withdrawal of this rejection is respectfully requested.

Claim 33 has been further rejected under 35 U.S.C. § 112, second paragraph, as being vague and indefinite because the antecedent basis for "the sample container" in line 4 is unclear. The Examiner contends that it is unclear which container is meant by the reference to "the sample container" in line 4 due to citing "a plurality of sample containers" in line 3. Applicants have amended claim 33 to replace "the sample container" with "each sample container" to more particularly point out that the reference to sample containers in line 4 is directed to each of the sample containers of the plurality specified in line 3. No new matter has been added by way of this amendment. The amendment to claim 33 is believed to be fully responsive to the Examiner's rejection of claim 33, as well as dependent claims 34 and 35, on this basis. Withdrawal of this rejection is respectfully requested.

Claim 33 has also been rejected as being vague and indefinite under 35 U.S.C. § 112, second paragraph, because the capillary tube has a sealed end, an open end, and another end. Applicants have amended claim 33 to clarify that the capillary tube has a sealed and an open end with a sealable closure on the open end. No new matter has been added by way of this amendment. The amendment to claim 33 is believed to be fully responsive to the Examiner's rejection of claim 33, as well as dependent claims 34 and 35, on this basis. Withdrawal of this rejection is respectfully requested.

The Examiner has also rejected claim 33 as being vague and indefinite under 35 U.S.C. § 112, second paragraph, because the phrase "the sample" in the last 9 lines of claim 33 lacks clear antecedent basis. Applicants have amended claim 33 in line 18 to replace "the sample" with "at least one selected PCR sample" to provide antecedent basis for the references to the "selected PCR sample," as amended, in lines 19-21 of claim 33. In this regard, applicants have further amended claim 33 to replace the references to the sample in lines 19-21 with the "selected PCR sample" to clarify the antecedent basis for this phrase. No

new matter has been added by way of these amendments. The amendments to claim 33 are believed to be fully responsive to the Examiner's rejection of claim 33, as well as dependent claims 34 and 35, on this basis. Withdrawal of this rejection is respectfully requested.

Finally, claim 33 has been rejected as being vague and indefinite under 35 U.S.C. § 112, second paragraph, because the phrase "the detected fluoresce" in line 24 lacks antecedent basis. Applicants have amended claim 33 to replace the phrase "the detected fluoresce" with "the detected fluorescence at the first and second wavelengths" to more particularly point out that the antecedent basis for this phrase is the fluorescence at the two wavelengths cited in lines 20-22. No new matter has been added by way of this amendment. The amendment to claim 33 is believed to be fully responsive to the Examiner's rejection of claim 33, as well as dependent claims 34 and 35, on this basis. Withdrawal of this rejection is respectfully requested.

Claim 55 stands rejected under 35 U.S.C. § 112 as being vague and indefinite because lines 16-21 cite a first and second holding means which are described as being monitored together whereas only one sample is specified in the monitoring position.

Applicants have amended claim 55 to replace the phrase "biological samples" with "first and second biological samples" in lines 16-19 and 21 to more particularly point out that two samples may be monitored when they are in the monitoring position. No new matter has been added by way of these amendments. The amendments to claim 55 are believed to be fully responsive to the Examiner's rejection of this claim on this basis. Withdrawal of this rejection is respectfully requested.

The Examiner has also rejected claim 55 under 35 U.S.C. § 112, second paragraph, as being vague and indefinite because a singular reaction is cited in the last two lines of claim 55 by the phrase "the biological reaction" which lacks clear antecedent basis

due to the practice of two sample holding means in claim 55. Applicants have amended claim 55 to specify first and second biological reactions in the preamble of claim 55 and in lines 16, 17, and 24. Applicants have also amended the preamble of dependent claim 56 to specify first and second biological reactions. No new matter has been added by way of these amendments. The amendments to claim 55 are believed to be fully responsive to the Examiner's rejection of this claim, as well as dependent claims 56-59, on this basis. Withdrawal of this rejection is respectfully requested.

Claim 56 stands rejected under 35 U.S.C. § 112, second paragraph, as being vague and indefinite. The Examiner contends that, similar to claim 55, only one monitoring position is cited whereas two samples are apparently being utilized. Applicants have amended claim 55 to clarify the relationship between the samples and the monitoring position. Claim 56 has been amended to be consistent with the amendment to claim 55. No new matter has been added by way of this amendment. The amendment to claim 56 is believed to be fully responsive to the Examiner's rejection of this claim. Withdrawal of this rejection is respectfully requested.

Claims 79-81 have been rejected under 35 U.S.C. § 112, second paragraph, as being vague and indefinite due to lack of a definition of the cooperativity between the cited chamber and sample vessels. Applicants have amended claim 79 to more particularly point out that the sample vessel holder is located within the chamber to define the cooperativity between the chamber and the sample vessels. No new matter has been added by way of this amendment. The amendment to claim 79 is believed to be fully responsive to the Examiner's rejection of this claim, as well as dependent claims 80 and 81, on this basis. Withdrawal of this rejection is respectfully requested.

In addition to the above-discussed rejection, claim 80 has been rejected under 35 U.S.C. § 112, second paragraph, because the cooperativity between the capillary tubes cited in claim 80 and the sample vessel of claim 79 is unclear. Applicants have amended claim 80 to replace "capillary tubes" with "sample vessels" in reference to the sample vessel of claim 79, and have further specified that the sample vessels of claim 80 are capillary tubes, to more particularly point out the cooperativity between the capillary tubes of claim 80 and the sample vessel of claim 79. No new matter has been added by way of these amendments. The amendments to claim 80 are believed to be fully responsive to the Examiner's rejection of this claim, as well as dependent claim 81, on this basis. Withdrawal of this rejection is respectfully requested.

Claim 82 has been rejected under 35 U.S.C. § 112 as being vague and indefinite because the phrase "the vessel" in lines 13, 17, and 21 of claim 82 lacks clear antecedent basis. The Examiner contends that it is unclear which vessel is meant as to the plurality of vessels cited in line 6. Applicants also have amended claim 82 to replace "said sample vessel" with "each of said sample vessels" in line 8 and "the vessel" with "each of said sample vessels" in line 13 to clarify that the antecedent basis for these phrases is the plurality of sample vessels cited in line 6. Applicants have amended claim 82 to replace the phrase "at least one of the sample vessels" with "at least one selected sample vessel" in line 15 to provide antecedent basis for the references to selected sample vessels in lines 17, 20, and 21, as amended. No new matter has been added by way of these amendments. These amendments to claim 82 are believed to be fully responsive to the Examiner's rejection of this claim. Withdrawal of this rejection is respectfully requested.

Claim 87 stands rejected under 35 U.S.C. § 112, second paragraph, as being vague and indefinite because the phrase "said device" in line 4 lacks antecedent basis.

Applicants have amended claim 87 by deleting the phrase "mounted in said device" obviating the Examiner's rejection. The deletion of this phrase also obviates the Examiner's rejection of dependent claims 88-92. Withdrawal of this rejection is respectfully requested.

Claims 33, 35, and 55-59 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wittwer et al. Applicants respectfully point out that references are only available as prior art under 35 U.S.C. § 103(a) if those references are prior art under 35 U.S.C. § 102. Under 35 U.S.C. § 102(b), a patent fails if "the invention was patented or described in a printed publication in this or a foreign country... more than one year prior to the date of the application for patent in the United States." Applicants respectfully submit that Wittwer et al. is not prior art because it was published after the date of the present patent application. The patent application was filed on June 4, 1997, while Wittwer et al. was published May 28, 1998. Attached as Exhibit A are the title page and copyright page for this reference, clearly showing a 1998 publication date. Applicants acknowledge that Wittwer et al. (cited reference "FB") was disclosed in an Information Disclosure Statement. However, Applicants now realize that its inclusion in the Information Disclosure Statement was in error. Because Wittwer et al. is not prior art for the purposes of this application, a rejection based on this reference is improper. Withdrawal of this rejection is respectfully requested.

Applicants note that the Examiner has objected to claims 25, 27, 28, 33, 35, 58, and 90 based on informalities. Applicants have adopted each of the Examiner's suggestions and have amended claims 25, 27, 28, 33, 35, and 90 to correct typographical errors and to point out more particularly that which applicants believe to be their invention. The Examiner's objection to the word "comprises" in claim 58 was withdrawn in a phone conversation with the undersigned on December 28, 1999. Withdrawal of the remaining objections is respectfully requested.



## **CONCLUSION**

The amendments and remarks presented herein are intended to fully address each of the Examiner's objections/rejections. In light of the amendments and remarks, the applicants respectfully request allowance of the pending claims and passage of the application to issuance.

Respectfully submitted,

Jill T. Powlick

Registration No. 42,088

JTP/rvb Indianapolis, Indiana 46204 (317) 231-7504

## EXHIBIT A

chnologies

## Gene Quantification

François Ferré *Editor* 

Foreword by Edwin M. Southern

Birkhäuser Boston • Basel • Berlin

gnostics

François Ferré The Immune Response Corporation Carlsbad, CA 92008, U.S.A.

Library of Congress Cataloging In-Publication Data

Gene quantification / François Ferré, editor : foreword by Edwin Southern. p. cm. - (Advanced biomedical technologies) Includes biographical reference and index. ISBN 0-8176-3945-4 (alk. paper). - ISBN 3-7643-3945-4 (alk. paper) 1. Quantitative genetics. 2. Gene amplification. 3. Polymerase chain reaction. I. Ferré, François. II. Series. QH452.7.G46 1997 572.8'6-dc21 97-21838

CIP

Printed on acid-free paper © Birkhäuser Boston 1998 Birkhäuser

Copyright is not claimed for works of U.S. Government employees.

All rights reserved. No part of this publication may be reproduced, stored in retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without prior permission of the copyright owner.

The use of general descriptive names, trademarks, etc. in this publication even if the former are not especially identified, is not to be taken as a sign that such names, as understood by the Trade Marks and Merchandise Marks Act, may accordingly be used freely by anyone. While the advice information in this book are believed to be true and accurate at the date of going to press, neither the authors nor the editors nor the publisher can accept any legal responsibility for any errors or omissions that may be made. The publisher makes no warranty, express or implied, with respect to the material contained herein.

Permission to photocopy for internal or personal use of specific clients is granted by Birkhäuser Boston for libraries and other users registered with the Copyright Clearance Center (CCC), provided that the base fee of \$6.00 per copy, plus \$0.20 per page is paid directly to CCC, 222 Rosewood Drive, Danvers, MA 01923, U.S.A. Special requests should be addressed directly to Birkhäuser Boston, 675 Massachusetts Avenue, Cambridge, MA\_

02139, U.S.A. ISBN 0-8176-3945-4 ISBN 3-7643-3945-4 Typeset by TypeSmith Graphic Services Printed and bound by Hamilton Printing Co., Rensselear, New York Printed in the Unitied States of America 987654321